

**REMARKS**

**I. Status of Claims**

Prior to this Amendment, claims 1-16, 18, 19, and 22-53 were pending and claims 2, 3, 16, 18, 19, 22, and 36-53 were under examination. In the Final Office Action dated August 24, 2006, the Examiner maintained the rejection of claims 2, 3, 16, 18, 22, and 36-53. By this Amendment, Applicants amend claims 2 and 16 and cancel claims 1, 3-15, 18, 19, and 22-53. Claims 2 and 16 are pending examination.

**II. Written Description Rejection under 35 U.S.C. § 112, first paragraph**

The Office maintained its rejection of claims 2, 3, 16, 18, 19, 22, and 36-53 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action at 3. The Office alleges that “[n]either the specification nor the claims teach the identity of the instantly claimed protein, or immunogenic compositions comprising said protein.” *Id* at 5. Applicants respectfully traverse.

The Office admits that SEQ ID NO:2 meets the written description requirement. *Id.* at 5, 7. Applicants have amended claim 2 so it now states, “An isolated or a purified protein involved in the virulence of a *Leishmania* parasite, wherein the protein has SEQ ID NO:2,” and claim 16 so it now states, “A composition comprising the protein according to claim 2 and a pharmaceutically acceptable carrier therefor.” Further, Applicants have canceled claims 1, 3-15, 18, 19, and 22-53. These amendments are not intended as and should not be considered as the Applicants agreeing with the Office’s rejection. Accordingly, Applicants respectfully request withdrawal of the rejection under the written description requirement of 35 U.S.C. § 112, first paragraph.

**III. Enablement Rejection under 35 U.S.C. § 112, first paragraph**

The Office also maintained its rejection of claims 2, 3, 16, 18, 19, 22, and 36-53 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. *Id.* at 10. The Office stated that the “specification lacks a clear demonstration that the protein of the instant claims is suitable for immunization.” *Id.* at 11. Applicants respectfully traverse.

Applicants have canceled claims 1, 3-15, 18, 19, and 22-53 and amended claims 2 and 16 such that they now are directed to “[a]n isolated or a purified protein involved in the virulence of a *Leishmania* parasite, wherein the protein has SEQ ID NO:2” and “[a] composition comprising the protein according to claim 2 and a pharmaceutically acceptable carrier therefor.” Further, amended claim 16 no longer references an immunogenic composition. These amendments obviate the Office’s rejection, but should not be construed as to suggest that Applicants are in agreement with the Office’s rejection. However, in light of these amendments, Applicants respectfully request that the Office withdraw its rejection under the enablement requirement of 35 U.S.C. § 112, first paragraph.

**IV. Rejection under 35 U.S.C. § 112, second paragraph**

The Office rejected claims 2, 3, 16, 18, 19, 22, and 36-53 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. *Id.* at 14. The Office made mention of the following: 1) in claim 2, the recitation, “wherein said protein is predominantly expressed in the most virulent isolates of the parasite;” 2) in claim 19, the recitation, “the Th1 type;” and 3) in claims 3, 16, 18, 19, 22, and 36-53, the

recitation of “an isolated protein” or “an immunogenic composition.” The cancellation of claims 1, 3-15, 18, 19, and 22-53 and the amendments to claims 2 and 16 obviate the Office’s rejection. Claim 2 and 16 no longer contain the objected to recitations. These amendments should not be considered an agreement on Applicants’ part with the Office’s rejection. Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

**V. Rejection under 35 U.S.C. § 101**

The Office rejected claims 2, 3, 16, 18, 19, 22, and 36-53 under 35 U.S.C. § 101 for allegedly being directed to non-statutory subject matter. *Id* at 15. Namely, the Office states that the claimed protein and sequence are not different from any found in nature and are not entitled to patent protection. *Id* at 16. Applicants respectfully traverse.

Claims 2, 3, 16, 18, 19, 22, and 36-53 pending prior to this Amendment and claims 2 and 16 as amended by this Amendment possess a characteristic not found in nature, i.e. being isolated or purified. In the Non-Final Office Action dated November 7, 2005, the Office at page 17, stated that insertion of the terms “isolated or purified” would obviate a rejection under 35 U.S.C. § 101. Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 101.

**VI. Objection under 37 C.F.R. § 1.75(c)**

The Office objected to claim 3 under 37 C.F.R. § 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Further, the Office states that the proper recitation is “SEQ ID NO:2,” not “SEQ ID No: 2.” Though not agreeing with the Office’s objections, Applicants have canceled

claim 3 and amended claim 2 to now recite “[a]n isolated or a purified protein . . . wherein the protein has SEQ ID NO:2.” Applicants submit that amended claims 2 and 16 are written in proper form. Accordingly, Applicants respectfully request that the Office withdraw the objection under 37 C.F.R. § 1.75(c).

## **VII. Conclusion**

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 2 and 16 in condition for allowance. Applicants submit that the proposed amendments of claims 2 and 16 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Finally, Applicants submit that the entry of the Amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

Applicants, therefore, request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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